

NEW PATENT APPLICATION
PRELIMINARY AMENDMENT

PATENT

Please add the following new claims to the application:

--13. In a biospecific assay method comprising

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- reacting microparticles coated with a bioaffinity reactant A which specifically binds an analyte to be assayed, a sample to be analyzed, and a labelled bioaffinity reactant B to cause said analyte and said labelled bioaffinity reactant B to specifically bind to said microparticles via the bioaffinity reactant A; and

- measuring signal strength from labelled bioaffinity reactant B bound to the microparticles to determine the analyte concentration in the sample, the improvement comprising:

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- contacting a predetermined amount of said sample, a predetermined number of uniformly sized microparticles coated with said bioaffinity reactant A and said labelled bioaffinity reactant B labelled with a luminescent label such that, after the specific binding of the analyte in the sample to said predetermined number of uniformly sized microparticles, each individual microparticle emits a signal strength that corresponds to the analyte concentration in the sample , and

- determining the analyte concentration in said sample by measuring the signal strength from individual microparticles using a measuring means capable of reading the luminescence from single microparticles, the number of individual microparticles measured

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being the minimum number that will provide a statistically reliable measurement of the signal strength, and comparing said signal strength with a standardization curve, wherein said standardization curve is a mean of the signal strength of said predetermined number of uniformly sized microparticles.

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14. The assay method according to claim 13, wherein an increasing sample volume is employed.

Sub D3
15. The assay method according to claim 13, wherein a decreasing sample volume is used.

Sub D2
16. The assay method according to claim 13, wherein the assay comprises a competitive immunoassay, in which the labelled bioaffinity reactant B is an antigen, and the bioaffinity reactant A comprises an antibody for whose binding sites the labelled antigen and an antigen of the analyte compete.

17. The assay method according to claim 16, wherein the amount of said predetermined number of uniformly sized microparticles coated with the antibody A is adjusted so that the lowest analyte concentration will result in the strongest signal.

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18. The assay method according to claim 13, wherein the microparticles used comprise a mixture of microparticles recognizing different analytes.--

Please amend claims 6, 7 and 10 as follows:

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6. (Amended) The assay method according to claim 13, [characterized by] wherein the assay [being] comprises a non-competitive immunoassay, in which the labelled bioaffinity reactant B is an antibody directed against [the] an antigen of the analyte.

7. (Amended) The assay method according to claim 13, [characterized by] wherein the assay [being] comprises a nucleic acid hybridization assay, in which the labelled bioaffinity reactant B is a nucleic acid probe.

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10. (Amended) The assay method according to claim 13, [characterized by the use] wherein said luminescent label is selected from the group consisting of labels emitting fluorescence, time-resolved fluorescence, chemiluminescence [or] and bioluminescence.